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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/332,803	06/14/1999	Ronald Vogels	4075US	3357

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/332,803

Applicant(s)

VOGELS, RONALD

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004 and 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-17, 72-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 and 73 is/are allowed.
- 6) ☒ Claim(s) 16, 72, 74, 75, 77, 79-83 and 85-88 is/are rejected.
- 7) ☒ Claim(s) 76, 78, 84, 89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The indicated allowability of claims 16 and 72 is withdrawn in view of the newly discovered reference(s) to Wickham et al., Armentano et al. and Roy. Rejections based on the newly cited reference(s) follow.

Priority for all pending claims is granted back to the filing date of the instant application (6/14/99). Specifically, support for a method for generating an adenoviral vector comprising a **sequence encoding an adenoviral capsid protein derived from two different adenovirus serotypes** as well as operably linking at least one E1 region coding sequence to a conditionally active promoter is granted back to the filing date of the instant application only because no written description can be found for these limitations in the parent application 09/065,752.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 72, 74, 75, 77, 79, 82 and 86-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Wickham et al.

Applicants claim a method for generating an adenoviral vector comprising welding together (which can be by homologous recombination in a mammalian cell) two nucleic acid molecules wherein said molecules comprise partially overlapping

sequences capable of combining with one another allowing the generation of a physically linked nucleic acid comprising at least two adenoviral ITRs, a functional encapsidation signal and a nucleic acid sequence of interest, at least one of said molecules comprising an adenoviral capsid (fiber) protein encoding nucleic acid derived from two different adenovirus serotypes.

Wickham et al. (WO 96/26281, publication date 8/29/96, see whole document, particularly pages 9-10, 12, 22-23) recites a method for generating adenoviral vectors comprising welding together two nucleic acid molecules having partially overlapping sequences by homologous recombination in mammalian cells (i.e. cells which have the receptor for the chimeric fiber and can replicate the adenoviral vector) so as to generate a single physically linked nucleic acid having the requirements for a adenoviral vector (i.e. two ITRs, encapsidation signal, a nucleic acid sequence of interest) and a sequence encoding a chimeric capsid comprising sequences from two different adenoviral serotypes. It is noted that applicants' example 1 on pages 22-23 involves generating adenoviral vectors that involve only adenoviral sequences and apparently have no overlap with a cellular nucleic acid. Wickham et al. therefore teaches the claimed invention.

Claims 16, 72, 74, 75, 79-82 and 86-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Armentano et al.

Applicants' invention is as described above. Additionally, in claims 80-81, applicants recite methods of making adenoviral vectors comprising chimeric adenoviral pentons or hexons.

Armentano et al. (WO 98/22609, published 5/28/98, see whole document, particularly pages 7, 11-12; Example 6; Claims 7-9 and 11-13) recites a method for generating adenoviral vectors comprising welding together two nucleic acid molecules having partially overlapping sequences by homologous recombination in mammalian cells so as to generate a single physically linked nucleic acid having the requirements for a adenoviral vector (i.e. two ITRs, encapsidation signal, a nucleic acid sequence of interest) and a sequence encoding a chimeric capsid protein, which can be a penton, hexon or fiber, comprising sequences from two different adenoviral serotypes. Armentano et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 72, 74-75, 79-80, 83 and 86-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Roy.

Applicants' invention is as described above. Additionally, claim 83 recites that at least part of the capsid protein is derived from an adenovirus subgroup B-type adenovirus.

Roy (US Patent 5,922,315, issued 7/13/99, filed 1/24/97, see whole document, particularly Column 3, lines 46-67; column 4, lines 1-67; column 6, lines 43-67; column 7, lines 1-56) recites a method for generating adenoviral vectors comprising welding together two nucleic acid molecules having partially overlapping sequences by homologous recombination in mammalian cells so as to generate a single physically linked nucleic acid having the requirements for a adenoviral vector (i.e. two ITRs, encapsidation signal, a nucleic acid sequence of interest) and a sequence encoding a chimeric capsid (hexon) protein, comprising sequences from two different adenoviral serotypes, one of which can be from the sub group B-type adenoviruses. Roy therefore teaches the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 85 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method for generating an adenoviral vector comprising welding together at least two nucleic acid molecules having partially overlapping sequences capable of recombining with each other to generate an adenoviral vector by linking complementary ends resulting from restriction enzyme digestion of the at least two molecules. The instant specification provides support for generating a adenoviral vector by homologous recombination between at least two molecules with overlapping sequences capable of recombining with each other to generate a vector and alternatively, by linking together complementary ends of two or more molecules generated by restriction endonuclease digestion. The instantly claimed method appears to be a hybrid of the two methods, welding together at least two molecules which have overlapping regions, not by homologous recombination, but by linking complementary ends generated by restriction endonuclease digestion. The instant specification does not provide support for the instantly claimed method. This is a NEW MATTER rejection.

Applicants' arguments with regard to the Deposit Declaration are persuasive. The Declaration filed 2/7/02 is sufficient. A new Deposit Declaration is not required and the outstanding 35 USC 112, 1st paragraph rejection is withdrawn.

Claims 17 and 73 are allowed.

Claims 76, 78, 84 and 89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
May 16, 2004


DAVID GUZO
PRIMARY EXAMINER